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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,177	10/29/1999	UPVAN NARANG	100448.01	6878

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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/04/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/430,177

Applicant(s)

NARANG ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 and 76-144 is/are pending in the application.
- 4a) Of the above claim(s) 4,13,14,26-49,76-110 and 122-144 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-12,15-25,50,51 and 111-121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, species c, claims 1-3, 5-12, 15-25, 50, 51 and 111-121 in Paper No. 25 is acknowledged. The traversal is on the ground(s) that there would be no burden on the examiner. This is not found persuasive because the invention of Group I is directed to a method of applying an agent to an applicator tip, whereas the invention of Group II is drawn to a method of making an applicator for adhesives, and the invention of Group III is directed to an applicator composition. The methods of Group I and Group II involve different steps and the composition of group III does not comprise a bioactive material or flavorant, which are part of the invention of Group II.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 5-12, 15-25, 50, 51 and 111-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung (WO 96//40797) in view of Engelson et al. (U.S. Patent 5,531,715).

Leung provides a method for applying polymerization initiators to an applicator tip, comprising dipping the applicator tip in a liquid medium, specifically a low boiling point solvent, containing

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the initiator and drying the applicator tip (See p. 17, line 18 to p. 18, line 15), and includes anionic surfactants, such as polysorbate 20 and polysorbate 80, poloxamers, cationic surfactants, such as tetrabutylammonium bromide, and amphoteric or zwitterionic surfactants, such as dodecyldimethyl(3-sulfopropyl) ammonium hydroxide, among the initiators used in the invention (See p. 16, lines 18-35). The alkylbenzyltrimethylammonium chloride claimed in claim 5 of the instant application, also known as benzalkonium chloride, is a cationic surfactant. Additionally, Leung includes alpha-cyanoacrylates, which are known as antifungals and antibacterial agents, among the polymerizable materials used in the invention (See p. 7, line 23 to p. 8, line 33) and initiators activated by stimulation, such as heat or light, among the initiators, which may be applied to the applicator tip (See p. 17, lines 14-28). The crystal violet claimed by Applicant in claims 7-9 of the instant application is activated by light.

Thus, Leung discloses a method comprising dipping an applicator tip in a solution comprising agents as claimed by Applicant in claims 1-3 and 5-12, and drying the applicator tip. Leung teaches that the liquid medium includes non-aqueous solvents, such as ether, acetone and ethanol, and mixtures thereof (See p. 17, lines 24-28). Thus, with regard to claims 1-3, 5-12 and 15-17, Leung provides the general teachings that the liquid medium is preferably a low boiling point solvent (See p. 17, lines 27-28), however, the prior art is deficient in the sense, that it fails to specifically include methanol among the solvents used in the invention. The examiner relies on Engelson et al. (See below) for the teachings that initiators may be dissolved in methanol.

With regard to claim 18, Leung teaches that the initiator on the applicator tip may be present in a variety of concentrations in the medium and the amount depends on process conditions (See p.

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17, lines 29-35). Regarding claims 19-25, 50 and 51, Leung teaches that the device of the invention comprises a container and a plunger for forcing the material from the container and an applicator tip (See p. 12, line 36 to p. 14, line 9), and the initiator may be applied to the applicator tip during the fabrication of the tip (See p. 18, lines 1-6) or the applicator tip may be detachable from the applicator container holding the polymerizable material (See p. 14, lines 10-20). Leung teaches that the applicator tip can be made of plastics, foams, rubber or film, and the material may be porous (See p. 15, lines 10-22).

With respect to claims 111-121, Leung teaches that the polymerizable material used in the invention, comprising alpha-cyanoacrylate (See p. 7, line 23 to p. 8, line 33), are useful as tissue adhesives, sealants for preventing bleeding or covering open wounds, systems for delivering bioactive agents and providing implants (See p. 19, lines 19-34), the tip may be a tube, cannula or catheter, and the container may be a syringe, a tube or a vial (See p. 13, line 20 to p. 14, line 9).

Engelson et al. discloses a method for applying a polymer coating to a catheter, comprising dipping the catheter into a solution comprising initiators dissolved in a solvent, which is preferably a low molecular weight alcohol and ether, especially methanol, ethanol and mixtures thereof (See col. 4, lines 31-67). Thus, ether, ethanol and methanol are considered equivalent in the art.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and compositions disclosed by Leung, by dissolving

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the initiator in methanol. The expected result would have been a successful method of applying an agent to an applicator tip and successful applicator tips. Because of the teachings of Leung, that the liquid medium is preferably a low boiling point solvent, and the teachings of Engelson et al., that ether, methanol, ethanol and propanol are considered equivalent in the art, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in providing an applicator tip with the desired agent. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

4. Applicant's arguments with respect to claims 1-12, 15-25, 50, 51 and 111-121 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

Sen83

October 29, 2003

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